UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/864,921	05/23/2001	John C. Reed	P-LJ 4752	1677

23601 7590 01/22/2004

CAMPBELL & FLORES LLP
4370 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122

EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/864,921	REED ET AL.	
	Examin r	Art Unit	
	Jeffrey Fredman	1634	

-- The MAILING DATE of this communication app ars on th cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) *9-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-8 in the paper filed November 21, 2003 is acknowledged. The traversal is on the ground(s) that Groups I and V lack a search burden because a search of Group I will identify art relevant to Group V. This is not found persuasive because different art relating to the method claims of Group V will need to be searched and that art would not need to be searched for Group I. Therefore, claims 1-8 will be examined and claims 9-30 are withdrawn.

However, since the Applicant has elected claims directed to the product, if the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is

found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

2. Applicant further traverses the sequence subgroup selection, because Applicant argues that SEQ ID NO: 97 encompasses each of the splice variants. This argument is not found persuasive because each of these splice variants is distinct, with different chemical properties, different issues relating to prior art, utility and enablement and encode different proteins. Therefore, the sequence subgroup selection is maintained and no other sequences are rejoined.

The requirement is still deemed proper and is therefore made FINAL.

Priority

3. It is noted that this application appears to claim priority to prior applications which were converted to provisional applications, but for which no number was given. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of

any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Objections

4. Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This claim is broader than the parent claim because it permits fragments of the claimed sequences, while the parent claim is limited to sequences which comprise the entirety of the specific sequence recited. For this reason, the 102 rejection below is applied to both claims 2 and 6, since the scope of claim 2 is construed to include claim 6, but claim 6 is clearly improper as failing to further limit.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

The current claims are drawn to a isolated nucleic molecules encoding polypeptides comprising SEQ ID NO: 97 and DNA which hybridizes to these seuqecnes.

Credible Utility

Following the requirements of the Utility Guidelines (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for Utility.), the first inquiry is whether a credible utility is cited in the specification for use of the nucleic acid molecule which encodes SEQ ID NO: 97. The only cited utilities identified by the examiner is a reach through utility to use the Clan-A (SEQ ID NO: 97)(see paragraph 0028) where Clan-A is used in interactions with other Card proteins in ways that "likely influence apoptosis, cytokine processing, or NF-kB activity (see paragraph 0043 of the specification)." These utilities are credible.

Upon identification of credible utilities, the next issue is whether there are any well established utilities for the nucleic acid molecule which encodes SEQ ID NO: 97, including 15-mer fragments of SEQ ID NO: 97. No well established utilities for this

nucleic acid molecule which encodes SEQ ID NO: 97 are identified in either the specification or in the cited prior art.

Substantial utility

Given the absence of a well established utility, the next issue is whether substantial utilities are disclosed in the specification. Here, there is no evidence of any substantial utility. No particular use for SEQ ID NO: 97 is found in the specification nor is there any use for any method involving SEQ ID NO: 97.

As noted in the utility guidelines, methods of treating unspecified diseases, basic research on a product to identify properties, intermediate products which themselves lack substantial utility are all insubstantial utilities (see page 6 of the Utility guideline training materials). If there were evidence of the association of SEQ ID NO: 97 with any disease state or with some other biological phenotype, this evidence might be considered regarding a substantial utility. However, no such evidence is found. In fact, the specification indicates that the Clan molecules can have opposing functions, so that some Clan molecules may trigger pro-caspase-1 activation while others may inhibit this activation. Further, even if the phenotype is pro-caspase-1 activation, this phenotype does not meet the requirements for a "substantial" utility since the specification provides no information on how to use such a phenotype.

Applicant's own paper supports a conclusion that there is no "real world" use, other than further investigation, for SEQ ID NO: 97. In Damiano et al (Genomics (2001) 75:77-83), Damiano states "Once their physiologic functions are uncovered, CLAN proteins may prove to be valuable therapeutic targets (see abstract)." So even

Applicant, at a time later than that of the submission of this application, indicates that the physiologic functions of CLAN proteins are unknown, and they "may" be valuable targets. Of course, depending upon the physiologic function, any protein "may" be a valuable target. It is the requirement of the 35 U.S.C. 101 that the invention submitted have utility when filed, not at some indefinite time in the future when further experimentation has reached its successful conclusion.

The cited utilities of pro-caspase-1 activation or inhibition have less "real world" significance than the amount of utility found insufficient by the Supreme court in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966). In Brenner, a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

> The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to polynucleotides encoding a protein (SEQ ID NO: 97) which has no identified cellular role, no particular cellular phenotype and is not associated with any disease. The function of the Clan-A (SEQ ID NO: 97) gene and its resulting protein are as yet undetermined with no known function or biological significance. Until some actual and specific significance can be attributed to the protein identified in the specification, or the gene encoding it, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Thus, there is no immediately apparent or "real world" utility as of the filing date directly consistent with *Brenner v. Manson*. Therefore, it is concluded that the claims lack substantial utility.

Specific Utility

In the current case, there is no specific utility for SEQ ID NO: 97 or methods using this sequence. No specific association of SEQ ID NO: 97 and any disease or even a specific biological phenotype is provided in the specification. The specification discusses a wide variety of phenotypes which might be influenced by Clan-A, SEQ ID NO: 97, such as cytokine processing, NF-KB activity or apoptosis (see paragraph 0043), but does not specifically teach any use for the sequence in association with these multiple generic possiblities. Even the claims are drawn to generic utilities as shown by nonelected claim 23, where the biological process includes elements ranging from apoptosis to inflammation, cell adhesion and, most generic of all, transcription. Potentially any fragment of nucleic acid is of commercial importance to someone, but this is not specific in any way to SEQ ID NO: 97.

Finally, with regard to the utility analysis, the current situation directly tracks Example 9 of the utility guidelines, where a nucleic acid of significantly unknown function was characterized as lacking utility.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Nature of Invention

Claims 1-8 are drawn to a system and method of screening using SEQ ID NO: 97. The nature of this invention relates to nucleic acids of a particular sequence with no other associated information. This is an invention in a subject area which is well recognized as unpredictable.

Breadth of the claims

The claims are drawn to a oligonucleotides which encode SEQ ID NO: 97, to fragments as small as 15 nucleotides from oligonucleotides which encode SEQ ID NO: 97 and to any sequence which will hybridize to an oligonucleotide which encodes SEQ ID NO: 97 under moderately stringent conditions.

Amount of Guidance in the Specification

The specification discloses the entire sequence of the SEQ ID NO: 97 and discloses one particular DNA sequence which encodes SEQ ID NO: 97, but identifies no particular use for the sequence. As noted in the utility rejection above, this utility is not found to be substantial nor specific and consequently, the specification provides NO guidance regarding how to use the oligonucleotide encoding SEQ ID NO: 97 or the broader embodiments of fragments and hybridizing oligonucleotides.

In fact, the specification indicates that "different isoforms of CLAN likely have opposing effects on pro-caspase-1 activation (see paragraph 0043)." Thus, the specification indicates that one cannot predict the function or use of the molecule based upon the sequence whatsoever. The specification here is admitting that even very closely related molecules may differ significantly in function.

Working Examples

There are NO working examples in which an oligonucleotide encoding SEQ ID NO: 97 is used in any assay for detection or diagnosis of any disease or any other related utility.

Amount of Guidance in Prior Art

As noted in the utility rejection above, the prior art provides no guidance with regard to the particular function of SEQ ID NO: 97. In fact, Applicant's own paper supports a conclusion that there is no "real world" use, other than further investigation, for SEQ ID NO: 97. In Damiano et al (Genomics (2001) 75:77-83), Damiano states "Once their physiologic functions are uncovered, CLAN proteins may prove to be valuable therapeutic targets (see abstract)." So even Applicant, at a time later than that

of the submission of this application, indicates that the physiologic functions of CLAN proteins are unknown, and they "may" be valuable targets. Of course, depending upon the physiologic function, any protein "may" be a valuable target. Damiano further notes "The physiological functions of the isoforms of CLAN remain to be delineated (see page 83, column 1)." It is the requirement of the 35 U.S.C. 112, first paragraph that the invention submitted have utility and be enabled when filed, not at some indefinite time in the future when further experimentation has reached its successful conclusion.

Skill in the Art

While no evidence is adduced, the examiner believes the skill in the art would be considered high.

Predictability of the Art

The art in biotechnology, as relates to the association of diseases with particular genes, is highly unpredictable. The claimed sequence is currently an orphan gene. Regarding such Orphan genes, Dujon (Trends in Genetics (1996) 12(7):263-270) notes that the most striking result of yeast sequencing is that "a significant proportion of yeast genes are orphans of unpredictable function (abstract)". Dujon further states "We have no clue to which direction to search and, even worse, when considering the experiments that could be done on orphans, we rapidly find ourselves intellectually embedded in the schemes of the past (page 2169, column 2)." Thus, it is extremely unpredictable what to do with an orphan gene such as SEQ ID NO: 97 in the absence of any defined utility.

Further, there is an abundance of evidence that very similar proteins can perform very different functions. For example, Rost et al (J. Mol. Biol. (2002) 318(2):595-608) notes regarding assignment of enzymatic activity based upon homology comparisons that "The results illustrated how difficult it is to assess the conservation of protein

function and to guarantee error-free genome annotations, in general: sets with millions of pair comparisons might not suffice to arrive at statistically significant conclusions (abstract)." Thus, even high levels of homology do not necessarily correlate with actual protein function.

So the prior art supports a finding that it is entirely unpredictable what use can be made of SEQ ID NO: 97 in the absence of any teaching in the specification.

Quantity of Experimentation

An immense amount of experimentation would be required in order to define whether this protein is associated with any particular disease state. In order to acquire statistically significant evidence of an association with a disease or other utility, dozens of patients in each of the many hundreds of different possible disease states would need to be subjected to collection of samples for analysis of their DNA, followed by analysis and the inventive efforts of determining if any association exists. This is a very large quantity of experimentation.

Determination

In view of the unpredictable nature of the invention, the absence of any guidance in the specification for a substantial and specific use, the absence of any working examples in the specification, the negative teachings in the prior art, the extreme unpredictability of the invention, and the large amount of experimentation necessary balanced against the high level of skill in the art and the relatively narrow breadth of the claims, it is concluded that undue experimentation would be required to use this invention as claimed.

Claim Rejections - 35 USC § 112 – Written Description

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register:

December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification, since the claims are not limited to any particular SEQ ID NO, but are open to a nucleic acid which hybridizes to a nucleic acid that encodes SEQ ID NO: 97 or which comprise 15 nucleotides of a particular Sequence. (With regard to claim 2, in view of the broadening effect of claim 6, this claim is included in the rejection since it may encompass fragments, as per the dependent claim). Most significantly, the genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID No 97. Thus, applicant has express possession of only one particular sequence in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains.

There is no showing or evidence which links structural limitations or requirements to any particular functional limitations. Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only specific nucleic and amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the nucleic acids as encoding an Clan-A protein lacks any specific structure, since it is in the absence of knowledge of the material composition.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound without identifying the structure function relationship of the compound, so that the compound is claimed solely as a

nucleic acid which hybridizes to a nucleic acid which encodes an SEQ ID NO: 97 without any additional functional limitations and without any definite structure.

In the instant application, SEQ ID NO: 97 is described. However, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise SEQ ID NO 97. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al (Genbank Locus AQ309404 (Dec. 22, 1998)).

Adams teaches an isolated nucleic acid molecule encoding a DNA that would hybridize to a nucleic acid encoding SEQ ID NO: 97 under highly stringent conditions (see attached alignment).

With regard to claim 3, there is not necessarily a difference between cDNA and genomic DNA in regions where there is no splicing. Since the sequence of Adams lacks a gap, it represents an identical sequence and anticipates the claim (see attached alignment).

With regard to claim 4, Adams teaches the vector pBELOBAC11 (see attached alignment).

With regard to claim 5, Adams teaches the availability of clones (see attached alignment).

With regard to claim 6 (and consequently claim 2 for the reasons given in the claim objection above), Adams teaches an isolated oligonucleotide which comprises at least 552 contiguous nucleotides of the nucleic acid molecule of claim 2.

With regard to claim 7, Adams teaches that the sequence is in a Bac vector, which comprises DNA, which is a detectable marker.

With regard to claim 8, Adams teaches that the clones are available from Research Genetics (see attached alignment).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Jeffrey Fredman
Primary Examiner
Art Unit 1634